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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,883	03/16/2001	David Thomas	TNX98-08-01	2201
26839	7590	10/24/2005	EXAMINER	
TANOX, INC. 10301 STELLA LINK HOUSTON, TX 77025			WEHBE, ANNE MARIE SABRINA	
			ART UNIT	PAPER NUMBER

1633

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,883

Applicant(s)

THOMAS ET AL.

Examiner

Anne Marie S. Wehbe

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47, 48 and 50-56 is/are rejected.
- 7) ☒ Claim(s) 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(d).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response also filed on 8/19/05 has been entered. Claims 1-46 are canceled. Claims 47-56 are currently pending in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in the previous office action.

Claim Rejections - 35 USC 112

The rejection of claims 53-57 under 35 U.S.C. 112, first paragraph, for scope of enablement, is withdrawn in view of applicant's amendments to claims 53 and 54 which now recite ITAM and ITIM species that are expressed on mast cells or basophils, and further in view of applicant's arguments regarding claim 55, i.e. that inhibiting B cell and T cell activation would have beneficial effects on allergic symptoms as both cell types contribute to allergic immune responses.

The rejection of claims 47-56 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of applicant's amendments to the claims.

Claim Rejections - 35 USC 102

The rejection of claims 47-48 and 51 under 35 U.S.C. 102(b) as being anticipated by Vossebeld et al. (1995) J. Biol. Chem., Vol. 270, No. 18, 10671-10679, is withdrawn in view of applicant's amendment to the claims which has deleted FcγRIII as an embodiment of an ITIM. The claims as amended are limited to wherein the ITIM is FcγRIIB or FcεRII.

Claim Rejections - 35 USC 103

The rejection of claims 47-48, and 50-56 under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (1997) J. Immunol., Vol. 158, 5065-5070, in view of EP 0 861 891 A1. (1998), hereafter referred to as Daeron et al., is maintained. Applicant's arguments have been fully considered but have not been found persuasive for reasons of record as discussed in detail below.

The applicant argues that Katz et al. does not teach using a bispecific antibody to crosslink the ITAM FcεRI with the ITIM FcγRIIB and that Daeron does not provide the requisite motivation to use a bispecific antibody because Daeron teaches away from the instant invention by stating that there are differences between ITIMs and particularly between KIR and FcγRIIB, citing example II in Daeron).

In response, the rejection of record clearly recognizes that Katz et al. does not teach using a bispecific antibody to achieve coligation of FcεRI with FcγRIIB resulting in mast cell inhibition. For this reason, the rejection of record cited Daeron et al. Further, the office disagrees that Daeron et al. teaches away from the instant invention. The previous office action cited Daeron et al. for teaching bispecific molecules that can be used to coligate and ITAM and an

ITIM. Like Katz et al., Daeron et al. teaches that both gp49B1 and Fc γ RIIB on mast cells contain ITIM domains and that coaggregation of these inhibitory molecules with the ITAM Fc ϵ RI results in mast cell inhibition (Daeron et al., page 9 and pages 13-14). Daeron et al. was further cited for teaching that bispecific molecules useful for coaggregating an ITAM and an ITIM include bispecific antibodies that are capable of cross-linking a stimulatory ITAM receptor and a ITIM receptor (Daeron et al., pages 14-15, claims 1-15). Daeron et al. also teaches that cross-linking of the ITAM and ITIM on a mast cell results in the modulation the release of inflammatory mediators and TNF-alpha (Daeron et al., page 14-15, especially claim 15). In regards to example II, on pages 11-12, the fact that Daeron et al. discloses that the mechanisms by which KIR and Fc γ RIIB inhibit Fc ϵ RI mediated activation of mast cells may be divergent does not teach away from the clear teachings in Daeron that both ITIM containing molecules do in fact inhibit Fc ϵ RI mediated activation of mast cells (see Daeron et al., pages 11-12, bridging sentence, and page 12, lines 8-12, and page 9, lines 28-41). Therefore, it is not agreed that Daeron teaches away from coaggregating Fc γ RIIB and Fc ϵ RI on mast cells.

Finally, the applicant states that the office has failed to establish a motivation to combine the references. In response, the rejection of record provides a clear motivation for combining the teachings of the references as follows: in view of the teachings of both Katz et al. and Daeron et al. that cross-linking the ITIM Fc γ RIIB and the ITAM Fc ϵ RI on mast cells results in the inhibition of mast cell activation, and particularly the inhibition of exocytosis of inflammatory molecules such as histamine and the release of TNF-alpha, and further in the view of the motivation to use bispecific antibodies to cross-link ITAM and ITIM on mast cells as taught by Daeron et al., it would have been *prima facie* obvious to the skilled artisan at the time of filing to

make a bispecific antibody containing a first determinant that binds to the ITAM FcεRI and a second determinant that binds to the ITIM FcγRIIB and to use that bispecific antibody to cross-link FcεRI and FcγRIIB on mast cells. Further, based on the teachings of both Katz et al. and Daeron et al. that cross-linking FcεRI and FcγRIIB on mast cells results in inhibition of mast cell activation, the skilled artisan would have had a reasonable expectation of success in using a bispecific antibody capable of cross-linking FcεRI and FcγRIIB to inhibit the release of histamine and TNF-alpha from mast cells, thus ameliorating allergic disease.

Thus, for the reasons set forth above, the rejection of record stands.

Claims Objections

Claim 49 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE, PH.D.
PRIMARY EXAMINER

